(12) UK Patent Application (19) GB (11) 2 090 115 A

(21) Application No 8138815
(22) Date of filing 23 Dec 1981
(30) Priority data
(31) 55/185079
(32) 27 Dec 1980
(33) Japan (JP)
(43) Application published 7 Jul 1982
(51) INT CL³ A23C 9/152
(52) Domestic classification A2B 323 421 423 424 601 603 604 613 BCX
(56) Documents cited None
(58) Field of search A2B

(71) Applicants
Snow Brand Milk Products Co. Ltd., 36—108, Naebo-cho 6-chome, Higashi-ku, Sapporo-shi, Hokkaido, Japan
(72) Inventors
Norio Kashiwabara, Hirotaka Maruyama, Tetuo Ishii, Satoru Kondo
(74) Agents
J. A. Kemp & Co., 14 South Square, Gray's Inn, London WC1R 5EU

(54) Nutrient composition suitable for enteral or oral feeding

(57) Conventional nutrient compositions which are administered enterally or orally to a patient pre- or post-operatively suffer from a variety of disadvantages, for example they can cause side effects such as diarrhoea. These problems are now overcome by a nutrient composition of the low-residue diet type comprising a protein source, fat source, carbohydrate source and, as desired, other nutritive component(s), the composition containing 20 to 40% by weight, based on the total weight of said protein, fat and carbohydrate sources and said other nutritive components, of skim milk powder as part of said protein source and 5 to 15% by weight, based on the total weight of said protein, fat and carbohydrate sources and said other nutritive components, of medium chain triglyceride as part of said fat source, said skim milk powder containing 5 to 30% by weight of lactose.

GB 2 090 115 A

SPECIFICATION

Nutrient composition suitable for enteral or oral feeding

The present invention concerns a nutrient composition suitable for oral and enteral feeding (tube feeding). "Enteral feeding (tube feeding)" herein refers to methods of so-called surgical nutrition used for pre- and post-operative care of patients by injecting nutrients via a feeding tube into the gastrointestinal tract of a patient for whom oral feeding of the nutrients is impractical.

Nutrient compositions for enteral feeding have been classified into elemental diet or chemically defined diet, synthetic low-residue diet and standard blended diet. An elemental diet contains purified crystalline amino acids as the nitrogen source. Other nutrient components such as essential fatty acids and vitamins are combined with the amino acids. A standard blended diet is prepared by combining milk or fruit juice with a fluidized mixture of various kinds of natural food. A synthetic low-residue diet is intermediate these two diets, and is in a powdery or a liquid state obtained by combining milk casein or egg-albumin as a protein source with a fat source, a carbohydrate source and, generally, inorganic salts and vitamins. It is used after dissolution in water or in its original liquid state as appropriate. The nutrient composition of the present invention belongs to the category of synthetic low-residue diets.

Although various products have hitherto been commerciallised as nutrient compositions for enteral feeding, they have the following demerits:

(1) many side effects causing diarrhoea, abdominal pains, feeling of abdominal distension, etc.;

(2) a rise in transaminase activity is caused, however only temporarily, after administration;

(3) their nitrogen balance is not favourable; and

(4) they taste bad and so are not suitable for oral administration, etc.

Some compositions have been commercialised with the intention of solving these disadvantages. For instance, the addition of lipids has been restricted to an extremely low level to control diarrhoea. However, as a result of trying to prevent side effects there may be insufficient nutrient supply.

It is for this reason that nutrient compositions suitable for enteral feeding without causing any side effects such as diarrhoea, etc. and which have good taste and can supply the necessary nutrients sufficiently, have not yet been developed.

Nutrient compositions for enteral feeding are also used, for example where a patient is suffering from impairment of deglutition, or where the patient's digestive tract in impassable in which case there is a necessity for early nutrient supplement after a surgical operation. Nutrient compositions are further used where long term care should be taken of a patient's nutritive state. Accordingly, there is a need for nutrient compositions which do not exhibit the disadvantages mentioned above.

For reference, nutrient compositions for enteral feeding hitherto reported or commercialised are exemplified as follows:

(a) A composition prepared by combining soy-bean, egg, skim milk, casein and essential amino acids as a protein source; vegetable fats and oils or medium chain triglyceride (MCT, a powdery or liquid triglyceride of a fatty acid of medium chain length) as a fat source; and alpha-starch, bread and dextrin as a carbohydrate source; to which water is added after addition of minerals and vitamins (SHOKUHIN KOGYO (Food industry), Vol. 22(12), page 41, 1979).

(b) A composition prepared by combining skim milk powder, whole milk powder, dextrin, maltose, electrolytes and vitamins.

(c) A composition prepared by combining dextrin, starch syrup solid, medium chain triglycerides and natural foods.

(d) A composition prepared by combining skim milk powder, tricaprylin, lactose and dextrin (Refer to "RINSHO—EIYOGAKU (Clinical Science of Nutrition) by OKABE, Kazuhiko et al., page 90, published in 1979".).

The present inventors have discovered that the prior art disadvantages are caused by lactose which is contained in a high amount (generally about 50 to 58% by weight) in the skim milk powder generally used as a protein source, the imbalance of amino acids within the protein source in the composition, and the insufficiency of the fat content of the composition. Further, they have found that the lactose content of the nutrient composition could be reduced by using 20 to 40% by weight of a low-lactose skim milk powder, containing 5 to 30% by weight of lactose, which is obtained by decomposing 50 to 90% by weight of the original lactose in the powder, as a part of the protein source. By doing this and by using 5 to 15% by weight of a medium chain triglyceride (MCT) as a part of the fat source the amino acid balance of the composition can be retained with an increase in the fat content of the composition.

It is thus possible to provide a nutrient composition for use in enteral feeding, which exhibits none of the disadvantages possessed by known nutrient compositions, which has an extremely low tendency to cause lactose intolerance and which is capable of supplying a high energy at a predetermined dose rate.

The characteristic feature of the present invention lies in a nutrient composition of a low-residue diet state containing a protein source, a fat source and a carbohydrate source as the base material, and having various trace nutrient components, in that the nutrient composition contains 20 to 40% by

weight of skim milk powder which contains a reduced amount of lactose by decomposing 50 to 90% by weight of lactose as a kind of protein source and 5 to 15% by weight of medium chain triglyceride as a fat source.

The low-lactose skim milk powder which is one of the main components of the composition of the invention and in which the content of lactose has been reduced by decomposing 50 to 95% by weight of lactose, can be prepared by subjecting a mixture of skim milk powder and water to the action of lactase to decompose a part of lactose in the skim milk powder. It is necessary that the extent of decomposition of lactose in skim milk powder is controlled to be 50 to 90% by weight, preferably, 70 to 85% by weight. In the case of the extent of decomposition of larger than 95%, the lactose content in the composition becomes so small that the maintenance of the necessary amount of lactose in the human body necessary for absorption of calcium becomes impossible. On the other hand, in the case of the extent of decomposition of lactose of less than 50%, the lactose content of the composition becomes excess and causing diarrhoea, abdominal pains and feeling of abdominal distension.

Medium chain triglyceride which is another main component of the composition of the present invention includes triglycerides of the fatty acids of 6 to 10 carbon atoms. Such triglyceride of the fatty acids of 6 to 10 carbon atoms shows the following specific properties as compared with triglycerides of the fatty acids of longer chain length of more than 12 carbon atoms: more rapid absorption in human body, no accumulation in the liver and reduction of cholesterol level in the body.

In addition, since the medium chain triglycerides can be easily mixed and emulsified with other fat sources such as vegetable oil such as corn oil, soybean oil, cotton-seed oil, safflower oil and sunflower oil or animal fats as milk fat or lard, it is possible to raise the fat content in the composition to the desired extent by combining the triglyceride with these fat sources.

The reason why the content of the skim milk powder which contains a reduced amount of lactose is defined in the range of 20 to 40% by weight in the composition is based on the easiness of retaining the amino acid balance in the composition by combining with other protein sources. As the protein sources used herein, milk casein and whole milk powder are suitable because of their good digestibility. In addition, purified crystalline essential amino acids may be combined with the composition, when necessary.

The reason why the content of the medium chain triglycerides (MCT) is defined to 5 to 15% by weight is to provide a nutrient composition with high calorie. In the case of the MCT content of less than 5% by weight, it is difficult to provide a nutrient composition with the desired high calorie even when other fat sources are combined, from the viewpoint of the absorption into the body, because the absorption of the fat sources other than the above-mentioned triglycerides are poorer. However, on the other hand, in the case of the content of larger than 15% by weight, the total content of fat source in the composition becomes in excess (more than 20% by weight) at the time when other fat source is combined for the supply of essential fatty acid such as linoleic acid. There is fear of causing diarrhea in the patient administered with such a composition.

Accordingly, it is necessary in the nutrient composition of the present invention to decide the combined amount of other fat source in connection with the content of the medium chain triglycerides.

Although in the composition of the present invention, both lactose remaining in the skim milk powder in which the content of lactose has been reduced and monosaccharides formed by the decomposition of lactose by lactase are present as carbohydrate, the amount of carbohydrate-supply due to them is insufficient and so it is necessary to combine separately another carbohydrate source with the composition.

The carbohydrate source used in the present invention includes various highly digestible carbohydrates, and since polysaccharide such as dextrin and starch syrup solid comprising water-soluble polysaccharides and dextrin restrain the raise of osmotic pressure of the composition of an aqueous solution type caused by the above-mentioned monosaccharides, they are preferable particularly. It is preferable to combine these carbohydrates in amount of 40 to 50% by weight of the nutrient composition.

In the present invention, in addition to the above-mentioned substances, inorganic salts, for instance, calcium salts, and iron salts and vitamins, for instance, vitamins A, B_1, B_6, C, D and E, nicotinamide, calcium pantothenate, folic acid, etc. as trace nutrient components may be added to the composition, and further, essential amino acids such as L-methionine, L-cystine and L-tryptophane may be added. Since in the composition of the present invention, essential amino acids derived from the above-mentioned protein sources are contained, in the time of adding the above-mentioned amino acids, it is preferable to control the amount of addition so that essential amino acid index (CAA index) becomes higher than 90. Further, as the above-mentioned inorganic salts, it is preferable to add in the form of calcium carbonate or iron and sodium succinate citrate. In addition, since the addition of other inorganic salts than calcium salt and iron salt raises the osmotic pressure of the composition of the present invention in the state of an aqueous solution, it is preferable to avoid such an addition.

Furthermore, since the nutrient composition of the present invention is applicable in oral feeding, components such as a fruit juice or flavor may be added.

In the case where the composition of the present invention is fed via a feeding tube to a patient

who cannot orally ingest because of various impairments, th composition is mixed with water and the concentration of th composition in the aqueous mixture is adjust d to about 25% by weight so that th mixture can flow smoothly through a thin tube. In this case, since it is desirable that the above-mentioned mixture has an energy of a little higher than about 1 kcal/ml, the energy of the nutrient composition at a solid state is preferably made to be 400 to 500 kcal/100 g of the solid composition. Taking the nutritive balance into consideration, it is preferable that about 15 to 25 g of protein component, about 13 to 18 g of fat component containing about 4 to 6 g of oil as the source of essential fatty acid and about 40 to 65 g of carbohydrate component are contained in 100 g of the nutrient composition in a solid state. It is preferable that about 2.5 to 3.5 g of inorganic mineral component and suitable amounts of vitamins and amino acids are further contained in the composition. The above-mentioned formulation can be altered in meeting the requirement of the patient's body.

The important merits of the nutrient composition of the present invention over the commercialized nutrient composition for enteral feeding are as follows:

(1) The composition of the present invention has very few side effects of causing diarrhea, abdominal pain and feeling of abdominal distention.

(2) A supply of the nutritive material of high contents of protein and fat can be prepared by the composition, and a higher energy can be supplied by a single administration of a limited amount.

(3) The raise of transaminase activity by the administration of the composition of the present invention is a little, and the administration of the present composition does not exert any harmful influence on the hepatic function.

(4) On ingesting the present composition, nitrogen balance becomes positive from just after the surgical operation and the nutritive state of the patient becomes favourable.

(5) The absorption of calcium contained in the present composition is favourable and the occurrence of lactose-intolerance due to the administration of the present composition is very rare.

The constitution and the effects of the present invention will be concretely explained by the following examples of execution and test:

EXAMPLE 1:

Preparation of the skim milk powder containing a reduced amount of lactose

After introducing 900 litres of water and 100 kg of skim milk powder into a decomposing vessel of a capacity of 2000 litres and mixing the content uniformly by stirring, 400 g of lactase was further added to the mixture uniformly. Lactose in the skim milk powder was subjected to decomposition by maintaining the temperature of the liquid mixture at about 7°C. About 200 litres of the specimen of the liquid mixture was collected three times, namely, after 7, 15 and 30 hours from the beginning of the decomposition, and each specimen was immediately spray-dried.

The extent of decomposition of lactose in each specimen was as follows:

Specimen No.	Hours of decomposition	Extent of decomposition of lactose (%)
1	7	55
2	15	75
3	30	90

EXAMPLE 2:

Preparation of the nutrient composition of the present invention

An aqueous mixture amounting to 1000 kg was obtained by adding 584 kg of water to 62 kg of milk casein, 1.3 kg of sodium carbonate for dissolving milk casein, 273 kg of starch syrup solid, 61 kg of medium chain triglyceride corresponding to 10% by weight of the product, 19 kg of corn oil, 13 g of vitamin A and D oil (containing both 500,000 I.U. of vitamin A and 50,000 I.U. of vitamin D per gram) and 15 g of dl-alphatocopherol (vitamin E). The solid content of the mixture thus prepared was 40% by weight. After pasteurizing and homogenizing the mixture, it was spray-dried to obtain 320 kg of the primary powder.

In th next place, by powder-to-p wder mixing of 65 kg of th primary powder, 28 kg of th specimen No. 2 obtain d in Example 1 (skim milk p wder in which lactose has been decomposed to the extent of 75% by weight) corr sp nding to 28% by weight f the product, 6 kg of whole milk powder, 150 g of L-methionine, 150 g f L-cystine, 60 g of L-trypt phan, 140 g of calcium carbonate, 50 g of iron and sodium succinate citrate, 0.5 g of vitamin B_1, 1 g of vitamin B_6, 10.2 g of vitamin C, 4.5 g of nic tinic acidamide, 3.4 g f calcium pant thenat and 90 mg of folic acid, a product of th present invention was obtained. The analysis of 100 g of the product thus obtained was as follows:

20 g of protein, 15 g f fat (consisting f 9.8 g of medium chain triglyceride, 3 g of com il and thers), 59 g f carbohydrate, 3.2 g of ash (c nsisting of 440 mg of calcium, 5 mg of iron and others), 1000 I.U. of vitamin A, 0.5 mg of vitamin B_1, 0.8 mg f vitamin B_2, 1 mg f vitamin B_6, 0.68 mg of vitamin B_{12}, 10.2 mg f vitamin C, 100 I.U. of vitamin D, 3.4 I.U. f vitamin E, 4.5 mg of nicotinamide, 3.4 mg of calcium pantothenate and 90 micrograms of folic acid, the presence of vitamin B_2 and vitamin B_{12} in the product being derived from raw materials.

The calorific value of this product was 444 Kcal/100 g.

EXAMPLE 3:

Preparation of the nutrient composition of the present invention

Another primary powder was prepared by at first making 1000 kg of an aqueous mixture of a solid content of 40% by weight by adding 584 kg of water to 64 kg of milk casein, 1.3 kg of sodium carbonate for dissolving milk casein, 275 kg of starch syrup solid, 31 kg of medium chain triglyceride corresponding to 5% by weight of the product, 45 kg of corn oil, 13 g of vitamin A and D oil (containing both 500,000 I.U. of vitamin A and 50,000 I.U. of vitamin D per gram) and 16 g of dl-alpha-tocopherol. After pasteurizing and homogenizing, the aqueous mixture was spray-dried.

In the next step, powder-to-powder mixing was carried out on 66 kg of thus prepared primary powder, 25 kg of the specimen No. 1 obtained in Example 1 of the extent of decomposition of lactose of 55% by weight (corresponding to 25% by weight of the product), 8 kg of whole milk powder, 190 g of L-cystine, 190 g of L-methionine, 60 g of L-tryptophane, 220 g of calcium carbonate, 50 g of sodium-iron succinate-citrate, 0.5 g of vitamin B_1, 1 g of vitamin B_6, 10.2 g of vitamin C, 4.5 g of nicotinamide, 3.4 g of calcium pantothenate and 90 mg of folic acid to obtain 100 kg of a product.

EXAMPLE 4:

Preparation of the nutrient composition of the present invention

In the first step, a primary powder was prepared by making 1000 kg of an aqueous mixture of a solid content of 40% by weight by adding 586 kg of water to 42 kg of milk casein, 800 g of sodium carbonate for dissolving milk casein, 273 kg of starch syrup solid, 76 kg of medium chain triglycerides (corresponding to 10% by weight of the product), 22 kg of corn oil, 13 g of vitamin A and D oil containing 500,000 I.U. of vitamin A and 50,000 I.U. of vitamin D per gram, and 15 g of dl-alpha-tocopherol. After pasteurizing and homogenizing, the aqueous mixture was spray-dried.

In the next step, powder-to-powder mixing was carried out on 56 kg of the thus prepared primary powder, 40 kg of the specimen No. 3 obtained in Example 1 of the extent of decomposition of lactose of 90% by weight (corresponding to 40% by weight of the product), 3 kg of whole milk powder, 190 g of L-cystine, 190 g of L-methionine, 60 g of tryptophan, 50 g of iron and sodium succinate citrate, 0.5 g of vitamin B_1, 1 g of vitamin B_6, 10.2 g of vitamin C, 4.5 g of nicotinamide, 3.4 g of calcium pantothenate and 90 mg of folic acid to obtain 100 kg of a product.

EXAMPLE OF CLINICAL TEST 1:

On administering each 150 ml of a 25% by weight aqueous mixture of the nutrient composition obtained in Example 2 to each of 30 postoperative patients via a feeding tube, no abnormal findings were observed except one case of diarrhea. However, according to the results of the same kind of experiment while using a commercialized product of the same kind, in 19 cases out of 30 total cases, abnormal findings such as diarrhea, abdominal pain and feeling of abdominal distention were observed.

From these results, it is understood that the nutrient composition of the present invention does not cause any conspicuous side effect and is excellent in effectiveness.

EXAMPLE OF CLINICAL TEST 2:

The organoleptic tests were carried out on the 100 hospitalized patients capable of oral ingestion. The samples were orally administered as each 150 ml of both of the two aqueous 25% by weight mixture at 38°C of the nutrient composition obtained in Example 2 and a commerciallized composition of the same kind. According to the tests, the numbers of the patients who evaluated each of the solutions as preferable was as follows on every item of the question:

	Item	Composition of present invention	Commercialized composition
1.	Easiness in drinking	81	19
2.	Taste	86	14
3.	Flavor	87	13
4.	Mouth feel	78	22
5.	Aftertaste	79	21

According to the above-mentioned results, it is seen that the composition of the present invention is superior to the commercialilized composition in all the items of evaluation and is also suitable for oral administration.

CLAIMS

1. A nutrient composition of the low-residue diet type, which composition comprises a protein source, fat source, carbohydrate source and, as desired, other nutritive component(s), the composition containing 20 to 40% by weight, based on the total weight of said protein, fat and carbohydrate sources and said other nutritive components, of skim milk powder as part of said protein source and 5 to 15% by weight, based on the total weight of said protein, fat and carbohydrate sources and said other nutritive components, of medium chain triglyceride as part of said fat source, said skim milk powder containing 5 to 30% by weight of lactose.

2. A nutrient composition according to claim 1, wherein said skim milk powder has been obtained by decomposing 50 to 90% by weight of the lactose originally contained in a skim milk powder.

3. A nutrient composition according to claim 1 or 2, wherein said protein source includes milk casein and/or whole milk powder.

4. A nutrient composition according to any one of the preceding claims, wherein said fat source includes one or more component selected from corn oil, soybean oil, cotton-seed oil, safflower oil, sunflower oil, milk fat and lard.

5. A nutrient composition according to any one of the preceding claims, wherein said nutrient composition contains 18 to 25% by weight of protein, 13 to 18% by weight of fat and 40 to 65% by weight of carbohydrate as solid matters.

6. A nutrient composition according to any one of the preceding claims which is in the form of an aqueous liquid.

7. A nutrient composition according to claim 6 which contains about 25% by weight of said protein, fat and carbohydrate sources and said other nutritive components.

8. A nutrient composition according to any one of claims 1 to 5 which is in the form of a powder.

9. A nutrient composition according to any one of the preceding claims wherein said skim milk powder has been prepared substantially as hereinbefore described in Example 1.

10. A nutrient composition substantially as hereinbefore described in any one of Examples 2 to 4.

Printed for Her Majesty's Stationery Office by the Courier Press, Leamington Spa, 1982. Published by the Patent Office, 25 Southampton Buildings, London, WC2A 1AY, from which copies may be obtained.